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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/663,620 | 09/15/2000 | Jay M. Short | DIVER1140-3 | 2110 |

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[REDACTED] EXAMINER

NASHED, NASHAAT T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1652 | 21 |

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|--------------------------------------|-------------------------------------|
| Application No. 09/663,620 | Applicant(s) Short, J. M. |
| Examiner Nashaat T. Nashed | Art Unit 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on May 27, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 170-238 is/are pending in the application.
- 4a) Of the above, claim(s) 172-174, 176-189, 202, 204-213, and 236 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 170, 171, 175, 190-201, 203, 214-235, 237, and 238 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 19 6) Other:

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2003 has been entered.

The application has been amended as requested in the communications filed May 27, 2003. Accordingly, claims 1-169 have been canceled, and new claims 170-238 have been entered.

New claims 170-238 are drawn to the same subject matter as those of canceled claims 1-169. The previously pending claims were subjected to a restriction requirement which included an election of species. All new claims read on the elected subject matter. Previously, Applicant elected glycosidase and gene shuffling as the enzymatic activity and a method of mutation, respectively.

Claims 170, 171, 175, 190-201, 203, 214-235, 237, and 238 are under consideration in this Office action. Claims 172-174, 176-189, 202, 204-213 and 236 are withdrawn from further consideration until a generic claim is found allowable.

Applicant is advised that should claim 203 be found allowable, claim 231 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 170, 171, 175, 190-201, 203, 214-235, 237 and 238 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,939,250 (250) in view of the prior art as exemplified by Stemmer *et al.* (see IDS, reference AE, U. S. Patent 5,605,793) for the reasons set forth in the prior Office action, papers numbers 9 and 14 in rejecting canceled claims 1-30, 32, 41-51, 53, 55, 57, 58, 63-87, 89, 98-111, 116, 117, and 119-169.

Claims 170, 171, 175, 190-201, 203, 214-235, 237 and 238 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,958,672 (672') in view of the prior art as exemplified by Arnold *et al.* (see IDS, reference AH, U. S. Patent 5,316,935) and Stemmer *et al.* (see IDS, reference AE, U. S. Patent 5,605,793) for the reasons set forth in the prior Office actions, papers numbers 9 and 14 in rejecting canceled claims 1-30, 32, 41-51, 53, 55, 57, 58, 63-87, 89, 98-111, 116, 117, and 119-169.

Claims 175, 190-201, 203, 214-235, 237 and 238 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-70 of U.S. patent application No. 09/375,605 (605) in view of the prior art as exemplified by Arnold *et al.* (see IDS, reference AH, U. S. Patent 5,316,935) and Stemmer *et al.* (see IDS, reference AE, U. S. Patent 5,605,793) for the reasons set forth in the prior Office action, paper number 9.1-30, 32, 41-51, 53, 55, 57, 58, 62-87, 89, 98-108, 111, 117, 126, 128, 130, 133-135, 140, and 143-169

Applicant appears to have accepted the obviousness-double patenting rejections and indicates his willingness to file a terminal disclaimer to overcome the above rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 170, 171, 175, 190-201, 203, 214-235, 237 and 238 are rejected under, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) Claims 170 is confusing because step (b) could have more than one meaning. The first is subject the entire screened library in (a) for mutagenesis, whereas the second meaning is select one or more clones from the library and subject them individually to mutagenesis to generate secondary libraries. The two meaning lead to two distinct methods. If the second interpretation of the claim is the one that the applicant intended, the claimed method would be an incomplete methods for omitting essential steps, such omission amounting to a gap between the steps for the reasons set forth in the prior Office action, paper number 9 and 14. If the first interpretation is adopted, the claimed method would be indefinite. For examination purposes only, both interpretations are adopted.
- (b) Step (c) in claim 170 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Step (c) of claim 170 is directed to expressing the library. It is not clear to this examiner which of the various libraries in the claim to which the applicant is referring.
- (c) Step (d) in claim 170 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons set forth in the prior Office action. The claim does not contain a step to identify and characterize a protein having an activity of interest before the mutagenizing step. Thus, it is unclear to this examiner how such a comparison step can take place.
- (d) The phrase "pooled prior to insertion into clones of the library" in claim 220 lacks antecedent bases in the claim from which it depend, and render renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons. First, there is no embodiment of claim 170 directed to insertion of nucleic acid clones. Second, the act of pooling nucleic acid is a selection process which directly negate an embodiment of claim 170, i. e., "obtained without selection".
- (e) the limitation wherein the library is generated from pooling individual gene libraries generated from the nucleic acid" in claim 221 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The act of pooling nucleic acid is a selection process which directly negate an embodiment of claim 170, i. e., "obtained without selection".
- (f) The phrases "the primers are labeled with detectable molecule" in claim 224, "the oligonucleotide labeled with a detectable molecule" in claim 225, and "probe labeled with a detectable molecule" in claim 238, steps (a) and (b), renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

A probe/primer is an oligonucleotide labeled with a detectable moiety. Since the detectable moiety is always covalently attached to the oligonucleotide, the detectable moiety can not possibly be a "molecule".

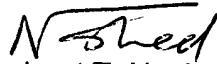
- (g) Claim 232 recites the limitation "screen further desired bioactivity" in the method of claim 170. There is insufficient antecedent basis for this limitation in the claim. Also, the phrase is confusing because of the role of a second "desired protein" to identify a first desired protein activity. Claim 232 is drawn to obtain single protein, i. e., "a modified protein having improved activity".
- (f) The phrase "a difference in the substrate before after contact" in claim 233 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. It is not clear to the examiner to what difference the applicant is referring.
- (g) Claims 171, 175, 190-201, 203, 214-219, 223, 226-231, 234, 235, and 237 are included in this rejection because they are dependent on rejected claims and do not correct the deficiencies of the claim from which they depend.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Nashed
Nashaat T. Nashed, Ph. D.
Primary Examiner